EXHIBIT 3

Statement of the National Alliance for Infusion Therapy, and the National Home Infusion Association, Alexandria, Virginia

The National Alliance for Infusion Therapy (NAIT) and the National Home Infusion Association (NHIA) -- representing providers and manufacturers of home infusion drug therapy supplies, equipment and services -- submits this statement for the hearing record for consideration by the Subcommittee of Health.

Home Infusion Drug Therapy

Home infusion drug therapy involves the administration of a drug through a needle or catheter. Typically, infusion drug therapy involves the full clinical management of patient care for those who require a drug therapy that is administered intravenously. It may also involve situations where drugs are provided through other parenteral (non-oral) routes. Infusion drug therapies are used only when less invasive means of drug administration are clinically unacceptable or less effective. Medications are administered by infusion only upon the prescription of a treating physician.

A team of clinical pharmacists, high-tech infusion nurses, patient service representatives and delivery and reimbursement professionals support patients and their caregivers throughout the treatment process. The services provided by the team are inextricably linked to the therapies and are often mandated by accrediting bodies whose standards ensure quality of care outside of the hospital setting, as well as by the professional standards of practice of the American Society of Health-System Pharmacists and the Intravenous Nurses Society. Due to the extremely sensitive and invasive nature of infusion therapies, the standards of practice are some of the most rigorous in the practice of pharmacy and nursing.

This high level of practice standards is also echoed in the facility requirements for the provision of home infusion drug therapies. Home infusion drug therapies must be prepared in high-tech, stringently controlled environments. Due to the nature of these therapies, in many cases the quality assurance standards even exceed hospital inpatient facility standards for preparation of intravenous medications.

In short, the professional pharmacy services, supportive staff infrastructure and practice expenses required to ensure the safe and effective administration of infusion therapies are extensive. Despite this extensive clinical infrastructure, home infusion drug therapy provides a safe, patient-preferred and extremely cost-effective alternative to inpatient treatment.

Medicare Coverage and Payment for Home Infusion Drug Therapy

Providers and suppliers of infusion drug therapies in the home setting are not paid separately by Medicare for the critical services and practice expenses described above. Medicare does not have a separate benefit for infusion therapy, but instead, infusion drugs provided in the home setting are covered exclusively under Medicare's benefit for durable medical equipment. The only items that are explicitly covered and reimbursed under this limited benefit are the drugs, equipment and supplies. Unlike other health care professionals who administer infusion and injectable drugs currently covered under Medicare Part B, providers and suppliers of home infusion drug therapies do not have a mechanism under Medicare that provides them with reimbursement for the services and facilities necessary to provide these therapies.

This is an extremely important point for policymakers to consider as they seek to reform outpatient drug reimbursement. Since the Medicare program does not explicitly reimburse pharmacists for their practice expenses and professional services (including such home infusion services as compounding),

pharmacists currently are "paid" for these costs and functions primarily through reimbursement for the drugs. Similarly, Medicare does not explicitly pay for nursing services provided by infusion therapy providers. A nurse performs many functions, including patient screening and assessment, patient training regarding administration of the pharmaceuticals and general monitoring of the patient's health status. To the extent that Medicare reimburses for such services, it is largely through the drug payment. As explained in greater detail below, reductions in drug payments must be accompanied by a contemporaneous re-allocation of payment for these necessary professional services. If drug payments are reduced drastically without such a re-allocation, Medicare beneficiaries will not be able to receive home infusion drug therapy because the costs of therapy will exceed by a large margin the available reimbursement for the therapy.

It is important to emphasize that none of the specialized pharmacy services are covered under any other Medicare benefit. In a minority of cases, Medicare home infusion patients may meet the "homebound" requirement and qualify for the home health benefit. In such instances, the nursing services described above might be covered under that benefit. For all other Medicare home infusion patients, the nursing services are not covered by the home health benefit. Likewise, the home health benefit does not cover the provision of drugs.

In contrast to Medicare, private sector insurance plans and private managed care plans have embraced home infusion drug therapy over the course of the last two decades, and commercially insured patients represent 70 to 80 percent of home infusion drug therapy patients. The private managed care community has recognized that infusion therapy administered in the home is a tremendous source of cost-savings, and the private sector provides coverage for a growing list of infusion therapies.

Private sector health plans and payers typically recognize the professional services and practice expenses necessary to provide infusion drug therapy in the outpatient setting through a separate "per diem" reimbursement that is paid for each day the patient is receiving therapy. This per diem payment is made in addition to the cost of the drug and nursing visit.

As home infusion drug therapy has become a staple of major medical coverage in the private sector, Medicare's refusal to see these therapies as anything other than the delivery of supplies and equipment is crossing a line from poor policy to surreal. Despite the uncontradicted and overwhelming evidence of the clinical need for these services, the Medicare program persists in defining these multifaceted drug therapies as requiring no greater effort than is involved in the delivery of a walker or wheelchair. Unless Medicare's coverage of these therapies is brought into line with the private sector, Medicare beneficiaries ultimately will suffer in two important ways. If the provision of therapy becomes limited to what Medicare actually covers, then the beneficiaries will suffer from seriously reduced levels of care. Or, more likely, suppliers will simply cease providing care to Medicare beneficiaries to avoid the consequences of providing substandard care.

Reliance on AWP to Calculate Reimbursement

NAIT and NHIA understand the criticism expressed by Members of this Subcommittee, as well as other Members of Congress, regarding the current practice of relying on average wholesale price (AWP) as a basis for calculating Medicare and Medicaid outpatient drug reimbursement. The imperfections of the AWP methodology are well-known and extensively documented.

It should be noted that the September 2001 General Accounting Office study highlighted that home infusion therapies represent only a small percentage of current Medicare Part B drug expenditures. As a result, the GAO "did not analyze the costs of infusion therapy drug provided in the home setting because

they do not account for a substantial share of Medicare drug spending or volume."

For the reasons stated above, at the present time the drug payments for infusion therapy subsidize other functions that the Medicare payment methodologies do not reflect appropriately. The costs of these services and functions far outweigh the costs of the drug product, but these costs are clearly lower than the charges that would be incurred if the patient received treatment in an alternate setting. For home infusion drug therapy, the drug payment is the only available payment mechanism for the services that are essential to providing good quality care. The long-standing use of AWP to determine reimbursement has masked the failure of Medicare and Medicaid payment policies to define and account for the service component.

If changes to the methodology used to calculate drug reimbursement result in substantially reduced drug payments, without corresponding changes to ensure adequate reimbursement for the service component of providing infusion therapies, the end result will virtually guarantee an inability of providers to continue to provide these services. Without the availability of home infusion services, Medicare beneficiaries will be treated in more costly settings.

Recommendations

We urge Congress to recognize the need for a meaningful analysis of all of the drugs, items, professional services, and facility requirements necessary to provide various types of drug therapies to beneficiaries in a manner that is consistent with the standard of care in this country and private accreditation standards. To restrict the analysis to the difference between drug acquisition cost and Medicare reimbursement is to examine only one small piece of the equation. Such a narrow analysis would fail to meet the overarching goal of using Medicare resources as judiciously as possible.

Before instituting drug payment reform, Medicare must accurately define infusion therapy and create quality standards based on the standards currently and widely used in the private sector. Medicare should then establish a fee schedule that reflects all the covered components of the therapies to accompany the AWP-based drug payment changes.

We look forward to working cooperatively with the Subcommittee to explore solutions that are in the best interests of the financial integrity of the Medicare program, as well as the best interests of the health care needs of the Medicare beneficiaries that rely on home infusion drug therapies.
